

REMARKS/ARGUMENTS

Applicant submits herewith a Two-Month Petition for Extension of Time Under 37 C.F.R. 1.136(a) and fee payment with PTO-2038.

Claims 1, 2, 3, 6, 7, 10, and 11 stand rejected Under 35 U.S.C. 102(a) as anticipated by Hill et al. (US Patent 7,122,040). However, the Office action mischaracterizes the inventions in key respects. While the Applicant's invention comprises a movable arm that contacts the tip of an angled needle, Hill et al. describe and claim a shuttle that "captures the suture thread after it exits [the] needle." (Hill et al., col. 3, lines 66 and 67). The distinction between moveable arm and shuttle is not merely a choice between synonyms but instead goes to the essential and different purposes, structures, and modes of operation of each apparatus.

The shuttle described and claimed by Hill et al. operates in a manner typical of shuttles used in stitching operations: it reciprocates on a linear path to move thread being incorporated in a running stitch. As stated by Hill et al., "the purpose of shuttle 36 is to capture suture thread 12' at the distal end and to bring the captured suture thread 12' to a proximal position, from which the operator may remove the suture thread 12' from the apparatus." (Hill et al, col. 4, line 49-52). Hill et al. intended their device for rapid placement of replacement heart valves with continuous sutures (see Hill et al., Fig. 2), avoiding the delay and difficulty caused by manipulation of a curved needle within the narrow confines of a heart valve and resulting creation of many individual sutures (see Hill et al., Fig. 1). Applicant is unable to locate any reference, explicit or implicit, by Hill et al. that the shuttle is in any way intended to mask the tip of the needle to avoid accidental tissue penetration.

Applicant's movable arm does not reciprocate on a linear path and plays no role in manipulating the suture thread. Instead, Applicant's movable arm is shaped and functions in a manner typical of mechanical arms: it is much longer than it is thick, it is attached to the apparatus at a proximal end, and force applied to it at the proximal end causes the distal end to swing or rotate. Its distal end is usually urged away from the needle by a

movable arm actuator located within the body and is swung into contact with the needle only when the device operator applies manual force to the actuator. In that instance, its purpose is to mask the needle tip to allow safe withdrawal of the needle from within an incision. In short, Applicant and Hill et al. describe and claim devices that utilize different mechanisms to achieve different purposes.

Section 2 of the Office action seems to invoke two different "movable arm actuator[s]" as grounds for anticipation. The first is "a moveable arm actuator that contacts the tip of the suture needle (see figure 10)." Putting aside for the moment the point that the shuttle is not an arm, Fig. 10 shows a hook that is "integral" with the shuttle (see Hill et al. col. 5, lines 58-59) and is "urged upward...into the suture capture zone created by the bend in the needle." (Hill et al., col. 5, lines 60-61). Hill et al. describe the "suture capture zone" in detail in col. 5, lines 35-56. In view of the purpose and operation of the hook and shuttle, contact would be unnecessary and probably undesirable. In any event, Applicant does not describe or claim a moveable arm actuator that "contacts the tip of the suture needle." Only the distal end of the Applicant's moveable arm contacts the needle; Applicant's moveable arm actuator resides within the body.

Elsewhere in section 2 the "moveable arm actuator" is described as comprising "a compression member, disclosed as a spring in col. 4, lines 10-12, which acts to move the arm to a closed or open position." In view of the previous discussion, Applicant respectfully maintains that "closed or open positions" have no meaning with respect to the apparatus of Hill et al., the purpose and operation of the shuttle being solely to retrieve suture thread and not to open or close anything. Indeed, the embodiments depicted by Hill et al. in Fig. 10 and Fig. 11 show the needle tip positioned well above the level of the shuttle, so that the needle tip remains exposed even when the shuttle has slid to its furthest extreme of travel and the hook sweeps past the needle. This is not an oversight or defect; protecting the needle tip is simply not a feature that Hill et al. considered necessary for heart valve surgery.

Applicant has amended claims 10 and 11 to clarify the nature of the claimed invention.

Because the Applicant's apparatus and the apparatus described and claimed by Hill et al. use different structures and modes of operation to achieve different ends, Applicant believes that Hill et al. does not anticipate Applicant's claimed invention. Applicant therefore respectfully requests that the rejection be reconsidered and withdrawn, and claims 1, 2, 3, 6, 7, 10, and 11 allowed.

Claim 19 stands rejected under 35 U.S.C. 102(b) as being anticipated by Gimpelson (US Patent 5,336,239). Since claim 19 is a means claim, this rejection must be supported by a *prima facie* case as described in MPEP 2183. Applicant requests an explanation and rationale as to how and why specific elements of Gimpelson are considered equivalent to specific elements claimed by Applicant. In the absence of such a case, Applicant respectfully requests that this ground for rejection be withdrawn and claim 19 allowed.

Claims 1-7 and 13 stand rejected under 35 U.S.C. 103(a) as unpatentable over Gimpelson (US Patent 5,336,239) in view of Forde (US Patent 2,692,415). Gimpelson fails not only to teach a moveable arm but to teach an arm at all. Instead, Gimpelson teaches a "bell" that "reciprocate[s] along a shaft" (Gimpelson, col. 3, lines 55-57). As a cup-shaped or saucer-shaped device a bell is structurally and functionally different from the narrow arm of Applicant's invention. One of the specific purposes of Applicant's invention is to avoid the use of a needle tip protector so large that it is itself difficult to move into and out of an incision. Gimpelson implicitly acknowledges this difficulty by treating use of the bell as optional (see Gimpelson, col. 5, lines 9-11 and claim 4).

Comparison between Forde's invention and Applicant's invention requires an even greater stretch of the imagination. Forde describes and claims an early attempt at a child-proof safety pin. A safety pin is, of course, intended for fastening rather than suturing, and therefore has a straight pin that is captured by a "labyrinthal" sheath. If such a straight pin was equipped with a passage for suture thread and used for suturing an incision, covering the tip would be worse than useless; whereas the arm of the Applicant's invention eases withdrawal without introducing awkward bulk into an incision, covering the tip of Forde's invention prevents both insertion AND withdrawal. A primary purpose

of Forde's "labyrinthal" sheath is to prevent the device from opening "save by a guided hand movement by one familiar with its manner of operation." (Forde, col. 1, lines 17-19). In fact, Forde's "movable arm" as referred to in section 5 of the Office action was deliberately bent into an awkward shape to make it difficult move into an opening (i.e., to swallow). Also, as a combined structure the "moveable arm pivotably mounted to the body of the needle" has no counterpart in Applicant's invention, wherein the body, arm and needle are separate components and the arm is not mounted on the needle, pivotably or otherwise.

As described in MPEP 706.02(j), a *prima facie* case of obviousness requires *inter alia* not simply a listing of claim elements but also a "teaching or suggestion to make the claimed combination and the reasonable expectation of success...both [of which must] be found in the prior art and not based on applicant's disclosure." Forde's motivation to trap his pin tip in a "labyrinthal" sheath goes to improvement of the usual function of a safety pin. It does not teach or suggest combination with Gimpelson's bell to create Applicant's invention, nor does Gimpelson teach or suggest a need for any modification of his bell. To the contrary, combination of the two would result in an inoperative device that would force a surgeon first to struggle to insert the needle into the sheath (a safety pin's "pin" must be guided by hand into its locked position), then to struggle further with a locked needle in the midst of an operation. Motivation to improve the function of a device (a safety pin) intended to perform a well-known and particular function (fastening cloth at a single point while remaining locked in place) does not translate into motivation to combine the device with another device (Gimpelson's bell) intended to perform an entirely different function (creating a series of sutures in human tissue).

Since neither reference plausibly teaches or suggests combination without the impermissible use of hindsight, and since such a combination would be largely inoperative, Applicant respectfully requests that this rejection be reconsidered and withdrawn and claims 1-7 and 13 allowed.

Claims 4, 5, 8, 9, 13, 14, 16, 17, and 18 stand rejected under 35 U.S.C. 103(a) as unpatentable over Hill et al. (US Patent 7,122,040) in view of Kirk III, et al. (US Patent

5,151,089). As observed above, Hill et al. disclose a shuttle rather than an arm. Kirk et al. disclose a needle sheath attached to a hypodermic syringe. The needle sheath is moved manually from a position against the body of the syringe to a position over the straight hypodermic needle. It is difficult to see, however, how that sheath would be combined with the suturing device of Hill et al. to produce Applicant's invention. If the Kirk's sheath was attached to Hill's shuttle it would prevent reciprocation of the shuttle. If Kirk's sheath was attached to Hill's barrel 32 at a point above the shuttle, the sheath would necessarily be so long that it could not be readily swung into position once the needle was inside an incision. If Kirk's sheath was attached to Hill's barrel 32 at a point below the shuttle (between the shuttle and the needle), the sheath would be difficult to reach, much less manipulate, and would require some additional undisclosed mechanism to hold it in place during withdrawal.

Speculation regarding even the possibility of combining the devices of Hill et al. and Kirk et al. is largely idle, however, because as has been previously observed, Hill et al. do not identify withdrawal of their device from an incision as a problem in need of a solution, and hence offer no motivation or suggestion to seek a sheath like that offered by Kirk, et al. Similarly, Kirk et al. address the problem of preventing accidental puncture with a syringe before and after a hypodermic injection is made. Kirk et al. do not contemplate a solution to the problem of withdrawing a J-shaped suture needle from an incision, and therefore likewise offer no suggestion or motivation for combination.

Claims 8, 9, 14 and 16 depend from claims that Applicant believes to be allowable and should therefore also be allowable.

Since neither reference plausibly teaches or suggests combination without the impermissible use of hindsight, and since the Office action offers no explanation of how such a combination could be operative, Applicant respectfully requests that this rejection be reconsidered and withdrawn and 4, 5, 8, 9, 13, 14, 16, 17, and 18 allowed.

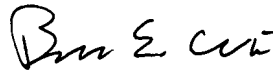
Claims 12 and 15 stand rejected under 35 U.S.C. 103(a) as unpatentable of Hill et al. (US Patent 7,122,040) in view of Kirk (US Patent 5,151,089) in further view of Hasson (US Patent 5,628,757). As previously argued, Hill et al. and Kirk et al. offer no

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teaching or suggestion for combination, and would probably produce an inoperative device if combined. Combination of Hasson with either Hill et al. or Kirk et al. to produce a design that facilitates ambidextrous gripping would be pointless since all three devices already appear to have bilateral symmetry. Applicant's claims 12 and 15 are for asymmetrical embodiments that are optimized for left-handed use (see specification paragraph 23). Applicant has amended claims 12 and 15 to clarify this distinction, and respectfully requests that the amended claims 12 and 15 be reviewed and allowed.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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